PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

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PCT

WRITTEN OPINION
(PCT Rule 66)

Date of mailing *(day/month/year)*	17.03.2004
Applicant's or agent's file reference: 031571woMetg	**REPLY DUE** **within 3 month(s)** from the above date of mailing

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/EP 03/06799	27.06.2003	28.06.2002

International Patent Classification (IPC) or both national classification and IPC
A61K39/095

Applicant
BRAUN, Jan Matthias ET AL.

1. This written opinion is the **first** drawn up by this International Preliminary Examining Authority.

2. This opinion contains indications relating to the following items:

I	☒	Basis of the opinion
II	☐	Priority
III	☒	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
IV	☐	Lack of unity of invention
V	☒	Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
VI	☐	Certain documents cited
VII	☐	Certain defects in the international application
VIII	☐	Certain observations on the international application

3. The applicant is hereby **invited to reply** to this opinion.

When? See the time limit indicated above. The applicant may, before the expiration of that time limit, request this Authority to grant an extension, see Rule 66.2(d).

How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

Also: For an additional opportunity to submit amendments, see Rule 66.4.
For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4 bis.
For an informal communication with the examiner, see Rule 66.6.

If no reply is filed, the International preliminary examination report will be established on the basis of this opinion.

4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: 28.10.2004

Name and mailing address of the International preliminary examining authority:

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I. Basis of the opinion

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed")*:

Description, Pages

1-56 as originally filed

Claims, Numbers

1-11 as originally filed

Drawings, Sheets

1/12-12/12 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
   ☐ the language of publication of the international application (under Rule 48.3(b)).
   ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   ☐ contained in the international application in written form.
   ☐ filed together with the international application in computer readable form.
   ☐ furnished subsequently to this Authority in written form.
   ☐ furnished subsequently to this Authority in computer readable form.
   ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
   ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   ☐ the description, pages:
   ☐ the claims, Nos.:
   ☐ the drawings, sheets:

5. ☐ This opinion has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been and will not be examined in respect of:

   ☐ the entire international application,

   ☒ claims Nos. 1,3-11(partially)

   because:

   ☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify):

   ☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

   ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

   ☒ no international search report has been established for the said claims Nos. 1,3-11 (partially)

2. A written opinion cannot be drawn due to the failure of the nucleotide and/or amino acid sequence listing to comply with the Standard provided for in Annex C of the Administrative Instructions:

   ☐ the written form has not been furnished or does not comply with the Standard.

   ☐ the computer readable form has not been furnished or does not comply with the Standard.

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-11
Inventive step (IS)	Claims	1-11
Industrial applicability (IA)	Claims	

2. Citations and explanations

see separate sheet

III. Non-establishment of opinion (Continuation)

For claims 1,3-11 a partial search report has been established by the International Search Authority. Therefore only those parts of the claims that have been searched will be the subject of the international preliminary examination (Rule 66.1(e) PCT.

V. Reasoned statement (Continuation)

2.1 CITATIONS

Reference is made to the following documents:

D1: JI YIN-DUO ET AL: 'The antigen specificity of meningococcal bactericidal antibodies induced by N. lactamica and N. meningitidis.' ZHONGHUA WEISHENGQUXUE HE MIANYIXUE ZAZHI, vol. 14, no. 4, 1994, pages 233-237, XP008013995 ISSN: 0254-5101

D2: WO 00 50074 A (GORRINGE ANDREW RICHARD ;HUDSON MICHAEL JOHN (GB); IMP COLLEGE SCH) 31 August 2000 (2000-08-31)

D3: EP-A-0 941 738 (AMERICAN CYANAMID CO) 15 September 1999 (1999-09-15)

D4: FR-A-2 782 642 (FORCEVILLE XAVIER) 3 March 2000 (2000-03-03)

2.2 NOVELTY (Art. 33(2) PCT)

2.2.1 D1 discloses bactericidal antibodies against Neisseria meningitidis serogroup A. LOS from Neisseria lactamica induce a good immune response to Neisseria meningitidis serogroup A in mice (see abstract). Thus, in view of D1, the subject-matter of claims 1,2,4,5,7,8 is not new.

2.2.2 D2 discloses the use of a commensal Neisseria (Neisseria lactamica) in a vaccine for the treatment of Neisseria meningitidis infection. The commensal Neisseria

may be used as a live vaccine or as a killed whole cell vaccine or in a vaccine containing fractions of Neisseria lactamica (e.g. outer membrane vesicles) or an immunogenic component thereof cross reacting with Neisseria meningitidis. The immunogenic component is e.g. a lipooligosaccharide. and can be administered by injection in combination with an adjuvant. D2 also discloses antibodies binding to a commensal Neisseria or to an immunogenic component thereof (e.g. LOS) for the treatment of a neisserial infection. Thus, in view of D1, the subject-matter of claims 1,2,4-7,9,10 is not new.

2.2.3 D3 discloses antigenic conjugates comprising a carrier protein bound to a conserved protein of a lipopolysaccharide of a gram negative bacteria e.g. Moraxella catarrhalis to elicit a cross reactive immune response to heterologous strains of gram negative bacteria e.g. Neisseria. D3 discloses also antibodies generated by these conjugates and use of these antibodies for passive immunisation and diagnosis (see abstract and paragraphs 0013,0014,0016-0018,0037-0039,0042-0044). Therefore, the subject-matter of claims 1-7,9-11 is not new.

2.2.4 The present application does not satisfy the criterion set forth in Article 33(2) PCT because the subject-matter of claims 1-11 is not new in respect of prior art as defined in the regulations (Rule 64(1)-(3) PCT).

2.3 INVENTIVE STEP (Art. 33(3) PCT)

2.3.1 Dependent claims 9 and 10 do not appear to contain any additional features which, in combination with the features of any claim to which they refer, involve an inventive step because the use of sodium selenite to reduce inflammation is disclosed in D4 (see page 4, line 4-5 and claims 1,3,6)

2.3.2 The present application does therefore not satisfy the criterion set forth in Article 33(3) PCT and the subject-matter of claims 1-11 does not involve an inventive step (Rule 65(1)(2) PCT).